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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/093,972	06/09/1998	JONATHAN W. NYCE	P6641031	7855

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EXAMINER

EPPS, JANET L

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 01/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/093,972

Applicant(s)

NYCE, JONATHAN W.

Examiner

Janet Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 108-129, 133-141, 146, 148, 151-156, 161, 163, 233 and 234 is/are allowed.
- 6) ☒ Claim(s) 130-132, 158, 159, 162, 164-173, 178-181, 183-189, 191-193, 195-198 and 200-232 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 108-131,133,134,146,148,151-156,158,159,161-173,178-181,184-189,191-193,195-198 and 200-234.

DETAILED ACTION

Response to Amendment

1. According to Applicant's amendment in the section entitled "THE PENDING CLAIMS" on page 2, Claims 108-131, 133-134, 146, 148, 151-156, 158-159, 161-173, 178-181, 184-189, 191-193, 195-198, and 200-234 are pending in the instant application. There is no amendment directing the cancellation of claims 132, 135-141, or 183, therefore it is unclear based upon Applicant's statements whether the claims are still pending or if they are to be cancelled. However, the claims will be treated on the merits as if still pending.

Claim Objections

2. Claim 108 is objected to because of the following informalities: The claim recites "a 5' or 3' junctions," this phrase is grammatically incorrect. It is likely that Applicants intended the phrase to recite, for example "a 5' or 3' junction" or the "5' or 3' junctions." Appropriate correction is required.

3. Claim 119 recites the term "xantine" this term is misspelled; the correct term is likely to be "xanthine."

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 130-131, 191 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 130-131, 191 appear to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. The metes and bounds of this Markush group is indefinite because it is unclear if the members of this group are mutually exclusive. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). In the instant case claim 191 recites redundant terminology, for example the terms "fatty acid" and "phospholipids" are recited in addition to reciting various species of said phospholipids and fatty acids in the same Markush group, for example omega-3 fatty acid, and phosphatidyl ethanolamine (phospholipid). Additionally, Claim 191 recites the terms "palmitic acid" and "palmitate," these terms are redundant since both terms refer to the same compound.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 132, 158-159, 162, 164-173, 178-181, 183-189, 191-193, 195-198, 200-232 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as filed provide support for respirable particles of .5 to 10 microns (μ) in size, and for nasal administration a particle size of 10-500 μ m (page 48, paragraph 2).

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Additionally, the specification as filed provides a description of the oligonucleotide useful in the methods and compositions of the present invention, wherein the preferred dosage for administration to a subject is about 0.01, 0.1, or 1 mg/Kg up to about 50, 100, or 150 mg/Kg.

The preferred concentrations of the oligonucleotide in the formulations of the present invention are from 0.05 to 50 μ M or more particularly 0.2 to 5 μ M. It is noted that neither reference to the oligonucleotides of the present invention is given in microns (μ). However, neither the specification as filed, nor the original claims provide support for the limitations wherein the "liquid or solid powdered formulation of particle size about 0.5 μ to about 500 μ ," or wherein the "liquid aerosol or spray formulation of particle size about 0.5 μ to about 10 μ or about 10 μ to about 500 μ of the nucleic acid."

Applicant's amendments to the claims raises the issue of new matter since the limitations recited in the claims as amended do not find support in either the original claims or specification as filed. Amendments to the claims must be made in such a way so as to have clear support or antecedent basis in the specification for any new terms appearing in the claims. MPEP 608.01(p)

8. Claims 164-168, 171-173, 178, 181, 183-189, 191-193, 195-198, 200-231 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using pharmaceutical compositions comprising antisense oligonucleotides targeting adenosine receptor mRNA effective in treating an asthmatic condition provoked by the administration of adenosine, does not reasonably provide enablement for the treatment of allergies or inflammation broadly, or for using pharmaceutical compositions comprising antisense targeting any other mRNA target other than adenosine receptor mRNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the

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invention commensurate in scope with these claims, for the reasons of record set forth in the Official Action mailed 11-07-2000.

As stated in the Official Action mailed 11-07-2000, the specification as filed fails to provide an enabling disclosure that would teach one of skill in the art how to treat inflammation, and allergies broadly, by the administration of a pharmaceutical composition comprising an antisense oligonucleotide targeting an unspecified mRNA target. The specification as filed provides adequate teachings regarding the treatment of lung allergies and/or inflammation associated with increased levels of adenosine by the administration of antisense targeting various adenosine receptor mRNA. However, the specification as filed does not enable anyone of skill in the art to practice the instant invention throughout the full scope of the claimed invention, wherein the claimed antisense oligos target unspecified mRNA targets. This conclusion is based upon the known unpredictability in the art regarding antisense based therapeutics, the lack of guidance, direction or description provided by the specification, the limited number of working examples provided by the specification, the breadth of the claims, and the amount of experimentation need to practice the invention.

9. Claims 108-129, 133-141, 146, 148, 151-156, 161, 163, and 233-234 are free of the prior art of record.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
Art Unit 1635

JLE
January 17, 2002



**SEAN MCGARRY
PRIMARY EXAMINER**